510(k) SUMMARY
(as required by 21 CFR 807.92(c))

JUN 5 2013

K130427 Pioneer Aspect Anterior Cervical Plate System

Sponsor:

Manufacturer: Pioneer Surgical Technology, Inc.
375 River Park Circle
Marquette, MI 49855

Official Contact: Sarah McIntyre, Regulatory Affairs Associate II
Phone: (906) 225-5861
Fax: (906) 226-4459

Date prepared: May 20, 2013

Name:

Trade/Device Name: Pioneer Aspect Anterior Cervical Plate System
Common Name: Anterior Cervical Plate System

Classification:

Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Product Code: KWQ
Regulatory Class: Class II

Description:

The Pioneer Aspect Anterior Cervical Plate System consists of an assortment of plates and screws. The screws are used to secure the plates to the vertebral bodies of the cervical spine through an anterior approach. The system consists of static plates in lengths that range from 10-105mm and include one, two, three, four, and five level designs. The plates have an integrated screw retention mechanism. The system includes fixed/variable self-tapping and self-drilling screws in Ø4.0 or Ø4.5mm, ranging from 10-20mm in length.

The purpose of this submission is to communicate the next generation Aspect Anterior Cervical Plate System to the Agency.

Intended Use:

The Pioneer Aspect Anterior Cervical Plate System is intended for anterior cervical fixation (C2-C7) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Material:

The plates and screws are manufactured from ASTM F 136 titanium alloy. The screw retention mechanism ("retaining clip") of the plate is manufactured from ASTM F2063 Nitinol.

Performance Data:

For a determination of substantial equivalence, non-clinical mechanical tests including ASTM F1717 dynamic and static compression bending and torsion static testing were completed. In addition, ASTM F543 screw pull-out testing and testing per internal protocols to assess screw pull through and retention characteristics were performed. Performance testing showed that the mechanical strength of the subject system is equivalent to or better than predicate devices and is therefore sufficient for the intended use.

Comparison to Predicate Devices

The Sponsor is claiming substantial equivalence to the following legally marketed predicate devices:

- K111528 Pioneer Aspect Anterior Cervical Plate System (24-series, SE 8/24/11)
- K100708 Pioneer Anterior Cervical Plate System (SE 6/4/10)
- K083663 Pioneer PACP (SE 2/25/09)
- K971883 Synthes Spine Small Stature Anterior Cervical Plate System (SE 10/16/97)
- K103491/K052552 DePuy Spine, Inc. SKYLINE Anterior Cervical Plate System (SE 2/14/11)

The subject Pioneer Aspect Anterior Cervical Plate System (27-series) has indications for use identical to those of the predicate Pioneer Anterior Cervical Plate Systems and employs the same principles of operation. Identical materials are used in predicate systems. Available screw lengths, screw diameters, plate prominence and width, and plate types (one, two, three, four and five-level; static) fall within the range of predicate devices. The differences between the subject and predicate device do not affect the substantial equivalence of the device, as demonstrated by a full battery of performance testing.

Performance and SE Determination:

Based on the supporting documentation within this premarket notification, the subject system demonstrates substantial equivalence to the listed predicate devices and is expected to be as safe, as effective, and perform as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 5, 2013

Pioneer Surgical Technology, Incorporated
% Ms. Sarah McIntyre
Regulatory Affairs Associate II
375 River Park Circle
Marquette, Michigan, 49855

Re: K130427
Trade/Device Name: Pioneer Aspect Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 5, 2013
Received: March 7, 2013

Dear Ms. McIntyre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K130427

Device Name: Pioneer Aspect Anterior Cervical Plate System

Indications:

The Pioneer Aspect Anterior Cervical Plate System is intended for anterior cervical fixation (C2-C7) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Prescription Use ___√___ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices